New drawings will be submitted with the labeling requirements of the Draftperson's Review.

Claim Objections

Claim 181 was objected to for grammatical reasons. Applicants have amended claim 181 to recite "claim 143" in place of "claims 143."

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 135, 161, 166 and 169, along with claims dependent therefrom, were rejected as indefinite for use of the term "mammalian" in the preamble of these claims. In response, Applicants have amended these claims to recite "human" in the preambles.

Claim 172 was rejected for indefiniteness for use of the term "membrane" when such term is not recited in parent claim 169. In response, Applicants have amended claim 172 to recite that the ABC1 polypeptide of claim 169 is in the membrane of an intact cell.

Claim 176 was rejected for indefiniteness for use of the term "mutant hABC1 polypeptide" without mentioning whether the mutant polypeptide has biological activity or the scope of the biological activities involved. In response, Claims 176 and 178 have been amended to recite that the mutant ABC1 has biological activity, as defined on page 15 lines 10-14.

Claim 184 was rejected as indefinite for use of the phrase "following said thereby." In response, Applicants have amended this claim to add the term "administering" after "following said."

Claim 168 was rejected as indefinite for dependence from cancelled claim 167. In response, Applicants have amended claim 188 to depend from claim 166.

Claim 188 was rejected as indefinite for dependence from cancelled claim 182. In response, Applicants have amended claim 188 to depend from claim 184.

Rejection Under 35 U.S.C. §112, First Paragraph (Written Description)

Claims 143-145, 148, 149, 151, 156-158, 176, 178-181, and 213-225 were rejected under section 112 as failing to meet the written description requirement.

The rejection continues to argue that, although the polypeptides are not being claimed, the specification fail to disclose a sufficient number of ABC1 polypeptides to show that Applicants were in possession of the invention. In response, Applicants have amended the generic claims to clarify the polypeptide involved.

Claim 143 (and claims dependent therefrom) has been amended to recite a biological membrane comprising an ABC1 polypeptide with at least 50% identity to the amino acid sequence of SEQ ID NO: 1 and having lipid transport activity. This amendment is supported by the disclosure of the application as filed, especially at page 15, lines 8-9, where an ABC1 polypeptide is defined as "a polypeptide having substantial identity to an ABC1 polypeptide having the amino acid sequence of SEQ ID NO: 1" and at page 12, lines 9-11, where "substantially identical" is defined as having at least 50% identity. Thus, in defining the percent identity with human ABC1 of SEQ ID NO: 1 and the activity being assayed, Applicants believe that the grounds of the rejection have been overcome.

Applicants have also added new claims 226-228 depending from claim 143 and limiting percent identity to, respectively, 85%, 90% and 95%. Claim 160 already recites use of the sequence of SEQ ID NO: 1.

Claim 213 (and claims dependent therefrom) has been amended to add the limitation of lipid transporting activity and at least 50% identity of the ABC1 to SEQ ID NO: 1. Some additional modifications were made to this claim for purposes of clarifying the recited process but do not change the claim elements.

Applicants have also added new claims 229-232 depending from claim 213 and limiting percent identity to, respectively, 85%, 90%, 95% and 100%.

Claims 176 and 178 were rejected on similar grounds. In response, Applicants have amended claim 176 (and thus claim 178 also) by adding the limitation that the mutant ABC1 has ABC1 biological activity, said activity being defined in the application at page 15, lines 10-14, as well as throughout the application.

The remaining rejected claims all depend, either directly or indirectly, from either claim 143 or claim 213, which have been amended.

Rejection Under 35 U.S.C. §112, First Paragraph (Enablement)

Claims 143-145, 148, 149, 151, 156-158, 176, 178-181, and 213-225 were rejected under section 112 as failing to meet the written description requirement.

The argument of the rejection is similar to that for written description: insufficient numbers of mammalian polypeptides have been disclosed in the application.

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In response, Applicants note that this is the same set of claims rejected under the written description rejection and Applicants' response is substantially the same as that above with the same amendments overcoming this ground of rejection also.

No fee is believed due in filing this response. If any fee is due, the Commissioner is requested to charge such fees, or credit any refunds, to Deposit Acc't No. 03-0678.

VIA FACSIMILE

Date: 9 January 2003

I hereby certify that this paper and the attachments hereto are being deposited today with the U.S. Postal Service "Express Mail Post Office To Addressee" service under 37 CFR 1.10 on the date indicated above addressed to:

BOX AF
Commissioner for Patents
Washington, DC 20231

Alan J. Grant 1/9/03
Alan J. Grant, Esq. **Date**

Respectfully submitted,

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AMENDED CLAIMS

135. (Three Times Amended) A process for identifying a compound that modulates ~~mammalian~~ human ABC1 (ABC1) polypeptide biological activity comprising contacting a compound with a human ABC1 polypeptide that has ABC1 biological activity and in the presence of adenosine triphosphate (ATP) under conditions promoting the biological activity of said ABC1 polypeptide and detecting a difference in said biological activity following said contacting relative to when said compound is not present

wherein said biological activity is binding or hydrolysis of adenosine triphosphate (ATP) and wherein said human ABC1 (hABC1) comprises amino acids 1-60 of SEQ ID NO: 1,

thereby identifying an ABC1 modulating agent.

143. (Four Times Amended) A process for identifying a compound that modulates mammalian ABC1 polypeptide biological activity comprising contacting a compound with a membrane comprising a mammalian ABC1 polypeptide comprising an amino acid sequence with at least 50% identity to the amino acid sequence of SEQ ID NO: 1 and having lipid transporting activity, in the presence of a lipid under conditions promoting transport of said lipid across said membrane, wherein said lipid is phospholipid or cholesterol, and detecting a difference in said transport following said contacting relative to when said compound is not present thereby identifying a mammalian ABC1 modulating agent.

161. (Three Times Amended) A process for identifying a compound that modulates ~~mammalian~~ human ABC1 polypeptide biological activity and is useful in modulating plasma cholesterol levels in a mammal comprising contacting a compound with a membrane comprising a human ABC1 polypeptide, wherein said polypeptide comprises amino acid residues 1-60 of SEQ ID NO: 1, and a source of one or more anions under conditions promoting transport of said one or more anions across said

membrane and detecting a difference in said transport following said contacting relative to when said compound is not present thereby identifying a mammalian ABC1 modulating agent.

166. (Three Times Amended) A process for identifying a compound that modulates ~~mammalian~~ human ABC1 polypeptide biological activity for use in treating CAD comprising contacting a compound with a membrane comprising a human ABC1 polypeptide and interleukin-1 under conditions promoting transport of said interleukin-1 across said membrane and detecting a difference in said transport following said contacting relative to when said compound is not present and wherein said human ABC1 comprises amino acids 1-60 of SEQ ID NO: 1, thereby identifying a mammalian ABC1 modulating agent useful for treating CAD.

169. (Twice Amended) A process for identifying a compound that modulates ~~mammalian~~ human ABC1 protein biological activity and is useful in modulating human plasma cholesterol levels comprising contacting a compound with a human ABC1 protein that has ABC1 biological activity and in the presence of a protein that binds to said human ABC1 protein under conditions promoting binding of said protein to said ABC1 polypeptide, wherein said human ABC1 protein comprises amino acids 1-60 of SEQ ID NO: 1, and detecting a difference in said binding following said contacting relative to when said compound is not present thereby identifying a mammalian ABC1 modulating agent.

172. (Twice Amended) The process of claim 169 wherein said ABC1 polypeptide is present in the membrane ~~is part~~ of an intact cell.

176. (Twice Amended) A process for identifying a compound that modulates mutant human ABC1 (hABC1) polypeptide biological activity comprising contacting a compound with a mutant hABC1 polypeptide having ABC1 polypeptide biological activity, comprising from 1 to 5 amino acid differences relative to the sequence of SEQ

ID NO: 1, and a member selected from the group consisting of a lipid, a protein, ATP, and interleukin-1, and detecting a difference in said biological activity following said contacting relative to when said compound is not present thereby identifying a mutant hABC1 modulating agent.

181. (Twice Amended) The process of ~~claims~~ claim 143 wherein said ABC1 polypeptide is a recombinant polypeptide.

184. (Twice Amended) A process for identifying a compound that modulates cholesterol levels in a mammal comprising administering to said mammal an effective amount of a compound that has ABC1 modulating activity in the process of claim 143 and determining a difference in cholesterol level in said mammal following said administering thereby identifying a compound that modulates cholesterol levels in a mammal.

188. (Twice Amended) The process of claim ~~182~~ 184 wherein said mammal is a human.

213. (Twice Amended) A process for identifying a compound that modulates lipid transport across a mammalian cell that includes a cell membrane that includes ABC1 polypeptide comprising an amino acid sequence with least 50% identity to the amino acid sequence of SEQ ID NO: 1 and having lipid transporting activity, comprising testing a said mammalian cell ~~that~~ wherein said cell includes ~~in the cell~~ a lipid selected from the group consisting ~~of~~ of phospholipid and cholesterol, under conditions promoting transport of said lipid across said membrane, and comparing transport of said lipid in the presence and absence of a test compound whereby a difference in said transport indicates modulation, thereby identifying said compound as a modulator of lipid transport.